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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,444	03/20/2001	Brent Iverson	MXGN:005USC2	3269

7590 01/04/2006
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EXAMINER

DO, PENSEE T

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,444

Applicant(s)

IVERSON ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-12, 15-26 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 11, 15, 16 and 46 is/are rejected.
- 7) ☐ Claim(s) 7-10, 12 and 17-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/14/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on July 14, 2005 has been acknowledged and entered.

Claims 1-3, 612, 15-26, and 46 are pending

Withdrawn Rejection(s)

Rejection under 112, 2nd paragraph is withdrawn herein.

Rejection under 102 (e) by Georgiou '867, Georgiou '344, and Higuchi '613 are withdrawn herein.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-9, 11, 15-20, 25, 26 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Slamon et al. (US 4,918,162).

Slamon teaches methods for identifying and monitoring human cancers. The methods rely on the detection of N-myc protein in a biological specimen, usually a cell sample such as tissue sample or sputum sample. Presence of the N-myc protein in the biological specimen may be diagnostic and/or prognostic of the cancer. Polypeptides and antibodies are used for detecting the N-myc proteins, where the polypeptides are associated with immunogenic sites on the protein. The polypeptides may be natural or

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synthetic. Such polypeptides include the N-myc protein in substantially pure form as well as fragments thereof. Monoclonal or polyclonal antibodies against the polypeptides are prepared by conventional techniques. Six polypeptides capable of eliciting antibodies useful in the present method have been identified. The method of synthesizing the polypeptides involves the expression in cultured cells of recombinant DNA molecules encoding a desired portion of the N-myc gene. Suitable cDNA and genomic libraries may be obtained from human cell lines known to contain the N-myc gene. (see col. 1, line 65-col. 2, line 48; col. 4, lines 36-49). The natural or synthetic DNA fragments coding for a desired N-myc fragment will be incorporated in DNA constructs capable of introduction to and expression in an in vitro cell culture. Usually, the DNA constructs will be suitable for replication in a unicellular host, such as yeast or bacteria i.e. negative bacteria E.coli. but may also be intended for introduction and integration within the genome of cultured mammalian or other eukaryotic cell lines. DNA constructs prepared for introduction into bacteria or yeast will include a replication system recognized by the host. Available expression vectors, which include the replication system and transcriptional and translational regulatory sequences together with an insertion site for the N-myc DNA sequence may be employed. (see col. 4, lines 62-68; col. 5, lines 1-15; col. 9, lines 65-66). The polypeptide can be an antibody or antibody fragment. The step of selecting a host cell that expresses the desired polypeptides comprises the steps of contacting said antibody or antibody-fragment-expressing cells with a selected antigen; and identifying a host cell that binds to said selected antigen (see col. 9, line 23-col. 10, line 14). The antigen/polypeptide is labeled

with a fluorescers, chemiluminescers, magnetic particles etc. (see col. 6, lines 58-68). The vector library is obtained by administering to an animal such as a mouse a desired antigen. The mouse is then killed, the spleen removed, and the spleen cells immortalized. DNA segments that encode distinct antibodies or antibody fragments were obtained and incorporated into a plurality of expression vectors, the vectors expressing antibodies or antibody fragments on the outer membrane surface of a Gram negative host cell, E. coli. (see col. 4, lines 62-68; col. 5, line 1-68). Selected cells that express a desired antibody are subjected to cleavage to release the selected antibody or antibody fragment from the surface of the outer membrane. (see col. 7, lines 27-50). Since the reference teaches eukaryotic cell, it is inherent that insect cell is included because insect cell is a eukaryotic cell.

Response to Arguments

Applicant's arguments filed July 14, 2005 have been fully considered but they are not persuasive.

Regarding the rejection by Slamon '162, Applicants argue that Slamon fails to teach a "library" of "vectors" or candidate polypeptides. Rather the reference teaches merely the recombinant expression of a few specific N-myc proteins. Second, there is no teaching of cell surface expression. The passage to which the examiner cites teaches away from cell surface expression, requiring release of the target either by "shed" of the proteins or "lysing" of cells. (col. 7, lines 27-36).

Slamon teaches "the vector library is obtained by administering to an animal such as a mouse a desired antigen". (see col. 4, lines 62-68; col. 5, lines 1-68). Selected cells

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that express a desired antibody are subjected to cleavage to release the selected antibody or antibody fragments from the surface of the outer membrane. (see col. 7, lines 27-50). Applicants assert that the passage on col. 7, lines 27-36 teaches away from the present invention by requiring a "releasing" step of the antibody/fragment. However, such step is not excluded by the present invention because the claims of the present invention contain opening claim language which encompasses extra step such as releasing the antibody/fragments after the host cell expresses the desired antibody/fragment. Surface expression is taught on col. 4, lines 62-68).

Allowable Subject Matter

Claims 10, 12, 21-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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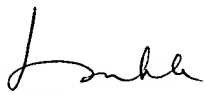
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
September 28, 2005


LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/27/05